BEST AVAILABLE COPY

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims alleging defective manufacturing and labeling of a medical device that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

QUESTION PRESENTED i
TABLE OF AUTHORITIES v
SUMMARY OF ARGUMENT 6
ARGUMENT 8
I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA 9
A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone* 9
B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims 12
1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims 12
2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices 13
C. Other Provisions of the FDCA Support Preemption of Common Law Claims 16
II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS 18
A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011 21
1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings 21
2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements 22

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings 24

B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device" 25

C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 27

III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS 31

A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011 32

1. The GMP Regulations Impose Significant Manufacturing Requirements 32

2. The 510(k) Process Imposes Significant Manufacturing Requirements 34

B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device" 34

C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011 35

1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims 35

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims.....38

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS.....38

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards.....40

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements.....44

C. The Obligation To Pay Damages Is A "Requirement".....47

CONCLUSION.....50

TABLE OF AUTHORITIES

CASES **Page**

American Airlines, Inc. v. *Wolens*, 115 S. Ct. 817 (1995) 15,18

Arkansas Louisiana Gas Co. v. *Hall*, 453 U.S. 571 (1981) 5

Baione v. *Owens-Illinois, Inc.*, 599 So. 2d 1377 (Fla. Dist. Ct. App. 1992) 29

Barnett Bank v. *Nelson*, No. 94-1837 (Mar. 26, 1996) 14,20,31

Bourjaily v. *United States*, 483 U.S. 171 (1987) 2

Brown v. *Gardner*, 115 S. Ct. 552 (1994) 11

Cadillac Fairview of Florida, Inc. v. *Cespedes*, 468 So. 2d 417 (Fla. Dist. Ct. App.), review denied mem., 479 So. 2d 117 (Fla. 1985) 39

Central Bank of Denver, N.A. v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439 (1994) 11

Chevron, U.S.A., Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) 15

Chicago & Northwestern Transportation Co. v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981) 10

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) 4,6,9,10,11,12,15

Coastal Petroleum Co. v. *American Cyanamid Co.*, 492 So. 2d 339 (Fla. 1986), cert. denied, 479 U.S. 1065 (1987) 13

CSX Transportation, Inc. v. *Easterwood*, 507 U.S. 658 (1993) 4,6,10,11

TABLE OF AUTHORITIES continued

Page

Duvall v. *Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), petition for cert. pending, No. 95-1010 29,30,35

Eli Lilly & Co. v. *Medtronic, Inc.*, 496 U.S. 661 (1990) 12

English v. *General Electric Co.*, 496 U.S. 72 (1990) 4,30

Feldt v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), petitions for cert. pending, Nos. 95-1037, 95-1214 26,29,30,35

Freightliner Corp. v. *Myrick*, 115 S. Ct. 1483 (1995) 30

Garcia v. *United States*, 469 U.S. 70 (1984) 2

Gile v. *Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) 43

Gillespie v. *United States Steel Corp.*, 379 U.S. 148 (1964) 5

International Paper Co. v. *Ouellete*, 479 U.S. 481 (1987) 10

Jones v. *Rath Packing Co.*, 430 U.S. 519 (1977) 45

Kennedy v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) 8

Kordel v. *United States*, 335 U.S. 345 (1948) 21

Lynnbrook Farms v. *Smithkline Beecham Corp.*, No. 92-2051 (7th Cir. Mar. 21, 1996) 42

Mayor of Georgetown v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91 (1838) 47

McDermott v. *Wisconsin*, 228 U.S. 115 (1913) 30

TABLE OF AUTHORITIES continued

Page

Mendes v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) 28,29,35

Merrell Dow Pharmaceuticals Inc. v. *Thompson*, 478 U.S. 804 (1986) 43,45

Michael v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995) 35

Moore v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) 25

Morales v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) 11,15,18

Murray v. *Briggs*, 569 So. 2d 476 (Fla. Dist. Ct. App. 1990), review denied mem., 581 So. 2d 165 (Fla. 1991) 39

Patterson v. *McLean Credit Union*, 491 U.S. 164 (1989) 11

Pension Benefit Guaranty Corp. v. *LTV Corp.*, 496 U.S. 633 (1990) 11

Pilot Life Insurance Co. v. *Dedeaux*, 481 U.S. 41 (1987) 5

Prather v. *Upjohn Co.*, 797 F.2d 923 (11th Cir. 1986) 29

Rodriguez v. *United States*, 480 U.S. 522 (1987) (per curiam) 2

San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959) 5,10

Silkwood v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984) 4

TABLE OF AUTHORITIES continued

Page

Stanley Industries, Inc. v. *W.M. Barr & Co.*, 784 F. Supp. 1570 (S.D. Fla. 1992).....29

State v. *First National Bank*, 660 P.2d 406 (Alaska 1982).....47

Texas & Pacific Railway v. *Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).....18

Underwriters at LaConcorde v. *Airtech Services*, 493 So. 2d 428 (Fla. 1986).....39

United Construction Workers v. *Laburnum Construction Corp.*, 347 U.S. 656 (1954).....4,5

United States Department of Treasury v. *Fabe*, 113 S. Ct. 2202 (1993).....41

United States v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 26, 1993).....22

United States v. *789 Cases*, 799 F. Supp. 1275 (D.P.R. 1992).....36

United States v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984).....23

United States v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977).....23

United States v. *James*, 478 U.S. 597 (1986).....2

United States v. *Park*, 421 U.S. 658 (1975).....37

United States v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992).....33

Witt v. *Norfe, Inc.*, 725 F.2d 1277 (11th Cir. 1984).....36,37

TABLE OF AUTHORITIES continued

Page

Zanzuri v. *G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990) 28

STATUTES

7 U.S.C. 4817 42
15 U.S.C. 1476(a) 42
15 U.S.C. 2075(a) 42
15 U.S.C. 2617(a)(2)(B) 42
21 U.S.C. 321(k) 21
21 U.S.C. 321(m) 20
21 U.S.C. 331 40
21 U.S.C. 331(q)(1) 47
21 U.S.C. 332 40
21 U.S.C. 333 40
21 U.S.C. 334 24,40
21 U.S.C. 336 47
21 U.S.C. 337 43
21 U.S.C. 343-1(a)(1) 41
21 U.S.C. 352 25
21 U.S.C. 352(a) 24
21 U.S.C. 352(f)(2) 24
21 U.S.C. 352(j) 24
21 U.S.C. 352(t) 47
21 U.S.C. 360c(d)(2)(A) 35
21 U.S.C. 360f 24
21 U.S.C. 360h 17,40,47
21 U.S.C. 360h(a) 24,31
21 U.S.C. 360h(a)(2) 28

TABLE OF AUTHORITIES continued

Page

21 U.S.C. 360h(b) 17
21 U.S.C. 360h(b)(3) 5
21 U.S.C. 360h(d) 7,17,18
21 U.S.C. 360h(e) 24,31
21 U.S.C. 360i 24
21 U.S.C. 360j(a) 25
21 U.S.C. 360j(f) 34
21 U.S.C. 360j(f)(1)(A) 32
21 U.S.C. 360j(f)(1)(B) 32
21 U.S.C. 360j(f)(1)(B)(ii) 32
21 U.S.C. 360j(f)(3) 32
21 U.S.C. 360k(a) ..... *passim*
21 U.S.C. 360k(a)(1) 12,20,25,46
21 U.S.C. 360k(a)(2) 2,12,20
21 U.S.C. 360k(b) 4,16
21 U.S.C. 360k(b)(1) 2
21 U.S.C. 360ss 43
21 U.S.C. 678 42
21 U.S.C. 1052(a) 42
21 U.S.C. 1052(b) 43
46 U.S.C. 4306 41
49 U.S.C. 30103(b) 41
Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991) 13
Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996) 13
La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991) 13

TABLE OF AUTHORITIES continued

Page

Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980) 13
Miss. Code Ann. § 11-1-63 (Supp. 1994) 13
Mont. Code Ann. § 27-1-719 (1993) 13
N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995) 13
Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996) 13
S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993) 13

REGULATIONS

21 C.F.R. 10.25 5
21 C.F.R. 10.30 5
21 C.F.R. 15.1(b) 32
21 C.F.R. 801.109 22,23,25,28,29
21 C.F.R. 801.109(a)(2) 23
21 C.F.R. 801.109(b)(1) 23
21 C.F.R. 801.109(c) 23,29
21 C.F.R. 807.81(a)(3) 22
21 C.F.R. 807.81(a)(3)(i) 22,34,38
21 C.F.R. 807.87(e) 21
21 C.F.R. 807.87(k) 21
21 C.F.R. 808.1(d)(1) 14
21 C.F.R. 808.1(d)(2) 39
21 C.F.R. 808.1(d)(6)(i) 48
21 C.F.R. 808.20(c)(1) 45
21 C.F.R. 820.5 33
21 C.F.R. 820.25 33
21 C.F.R. 820.46 33

TABLE OF AUTHORITIES continued

Page

21 C.F.R. 820.56 33
21 C.F.R. 820.60 33
21 C.F.R. 820.61 33
21 C.F.R. 820.80 33
21 C.F.R. 820.81 33
21 C.F.R. 820.100 33
21 C.F.R. 820.101 33
21 C.F.R. 820.115 33
21 C.F.R. 820.116 33
21 C.F.R. 820.120 33
21 C.F.R. 820.121 33
21 C.F.R. 820.130 33
21 C.F.R. 820.160 33
21 C.F.R. 820.161 33
21 C.F.R. 820.162 33
21 C.F.R. 820.180 33
21 C.F.R. 820.181 33
21 C.F.R. 820.182 33
21 C.F.R. 820.184 33
21 C.F.R. 820.185 33
21 C.F.R. 820.195 33
21 C.F.R. 820.198 33
21 C.F.R. 895.25 24,31
21 C.F.R. 895.25(a) 24
21 C.F.R. 895.25(a)(3) 24
21 C.F.R. 895.25(b) 24
21 C.F.R. 895.25(d) 24
28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9) 45

TABLE OF AUTHORITIES continued

Page

28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(10) 45
42 Fed. Reg. 30,383 (June 14, 1977) 48,49
43 Fed. Reg. 18,661 (May 2, 1978) 48,49
43 Fed. Reg. 31,508 (July 21, 1978) 37
58 Fed. Reg. 57,614 (Oct. 26, 1993) 34

OTHER AUTHORITIES

121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975) 42

Alexander Bickel, *The Least Dangerous Branch* (1962) 19

Arthur N. Levine, FDA Enforcement Manual (Apr. 1994) 44

Device Good Manufacturing Practices Manual, HHS Pub. No. FDA 87-4179 (Nov. 1987) 32

Device Labeling Guidance, FDA General Program Memorandum #G91-1 (Mar. 8, 1991) 22

FDA 510(k) Clearance Letter K914966 (May 13, 1992) 22

FDA Compliance Program Guidance Manual (Mar. 5, 1995) 33

FDA Draft Guidance for Format and Content for Premarket Notification 510(k) (Mar. 23, 1994) 22

FDA Enforcement Manual Monthly Bulletin (Nov. 1994) 33

H.R. 9984, 93 Cong., 1st Sess. (1973) 42

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) 2,26

TABLE OF AUTHORITIES continued

Page

Mark Herrmann & Geoffrey J. Ritts, *Preemption & Medical Devices: A Response to Adler & Mann*, 51 Food & Drug L.J. 1 (1996) 9,13,18

Robert S. Adler & Richard A. Mann, *Preemption & Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994) 9

U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved (GAO/PEMD-88-14, Aug. 1988) 21

BRIEF FOR CROSS-RESPONDENT MEDTRONIC, INC.

This case involves the construction of 21 U.S.C. 360k(a), the preemption provision of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Medtronic and plaintiffs have taken two markedly different approaches to that question of statutory interpretation. This Court's choice between those two approaches will go a long way toward deciding this case.

Medtronic's approach focuses carefully on the statutory language and structure, and uses legislative history and policy considerations only to reinforce the statute's text or to help clarify its terms. See Pet. Br. 12-49.[1] In contrast, plaintiffs' approach (and that of most of their amici) is dominated by policy arguments, often phrased in the form that a Congress reacting to incidents involving the Dalkon Shield *could not* have intended particular results (e.g., Cross-Pet. Br. 29); by inferences from the *silence* of legislative history (e.g., *id.* at 30); and by *subsequent* "legislative history" and subsequent congressional *inaction* on proposed legislation (e.g., *id.* at 33 n.12). When plaintiffs and most of their amici do pay attention to the statutory language, they do so only by misreading expansive language as if it contained words of narrow limitation. For example, they read the broad statutory phrase "any requirement applicable under this chapter to the device" as if it meant any *safety-ensuring* requirement, see U.S. Br. 19-20, and conclude that a requirement is *not* "applicable to the device" merely because it also applies to things other than the device, see Cross-Pet. Br. 41-42.

---

[1] This brief uses the same abbreviations (such as MDA, FDCA, and 510(k) process) used in Medtronic's opening brief. In addition, in this brief "Pet. Br." refers to Medtronic's opening brief, "Cross-Pet. Br." refers to plaintiffs' opening brief, and any citations to amicus briefs use an abbreviated form of the name of the party listed first on the brief.

Plaintiffs' approach to statutory interpretation is not legitimate. This Court "assume[s] that the legislative purpose is expressed by the ordinary meaning of the words used," *United States* v. *James*, 478 U.S. 597, 604 (1986); is "not willing to narrow the plain meaning of * * * [a] statute on the basis of a gestalt judgment as to what Congress probably intended," *Garcia* v. *United States*, 469 U.S. 70, 78 (1984); and will not take the "extraordinary" step of "requir[ing] legislative history to *confirm* the plain meaning of" a statute, *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). As the Court has explained, "no legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam).

Plaintiffs focus exclusively on the congressional intent to protect consumers from unsafe and ineffective devices and *completely ignore* the congressional intent to promote availability and innovation of devices by prohibiting state requirements through the preemption provision. Compare Cross-Pet. Br. 2-3, 11 with Pet. Br. 1-10 and U.S. Br. 2. By focusing on only one of Congress's several objectives, plaintiffs entirely disregard the congressional intent to enact a "balanced regulatory proposal," H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976), and thereby overlook the purpose of *the FDCA preemption provision*—enhancement of public health by preventing state regulation from stifling innovation of, and access to, critical medical technologies. See Pet. Br. 1-5, 46-49; PLAC Br. 4-8. The congressional balance of interests is manifest in the language of the preemption provision, which prohibits state device requirements "relat[ing] to * * * safety or effectiveness," even if the state requirements would be "more stringent" than applicable federal requirements. 21 U.S.C. 360k(a)(2), (b)(1).

Plaintiffs not only stress one congressional objective repeatedly to the exclusion of others, but also they overlook the *means* Congress selected to carry out the goal of protecting consumers from unsafe and ineffective devices. Plaintiffs incorrectly imply that the congressional intent to protect consumers necessarily requires compensation through tort remedies. But Congress instead chose to protect consumers by giving the FDA significant new authority to impose substantive safety and effectiveness requirements, remove dangerous devices from the market, and control market entry through premarket clearance processes. See Pet. Br. 5-10. Because the MDA substantially *enhanced* consumer protection by imposing new federal requirements, plaintiffs are simply incorrect in asserting that the statute's preemption of common law claims leaves consumers with less protection than they had before the MDA's enactment.[2]

Even if one were willing to join plaintiffs in speculating what Congress *could* or *could not* have intended, there would be no reason to doubt that Congress meant what it said in the encompassing words of the statute, i.e., meant to preempt *all* state "requirements"—including those imposed by the common law—that are "different from, or in addition to," *any* applicable FDCA requirement and that relate to safety or effectiveness *or* to another matter covered by an applicable FDCA requirement. Members of Congress thinking rationally about the *benefits* that thousands of safe and effective medical devices provide millions of consumers—and not just focusing obsessively on the well-

---

[2] Attempting to minimize the significance of these comprehensive federal requirements, plaintiffs erroneously suggest (e.g., Cross-Pet Br. 35-36) that devices cleared through the 510(k) process put the public at risk through inadequate premarket scrutiny of safety and effectiveness. This assertion fundamentally contradicts their contention that Congress enacted the MDA as "landmark legislation" addressed solely to consumer protection. In any event, as Medtronic explained in detail in its opening brief, the statute created multiple safeguards applicable to 510(k) devices. See Pet. Br. 8-10, 23-27; see also HIMA Br. 3-22.

publicized problems of a *single* device, the Dalkon Shield—could easily conclude that the best approach to regulation was to concentrate it in one federal agency, capable of considering both costs and benefits, and not to allow states to supplement such intensive federal regulation with additional state "requirements," *especially* not state requirements imposed by ad hoc decisions applying the generalities of the common law to individual circumstances. Members of Congress also easily could be concerned about the effect of state regulation (including application of the common law) on product availability and innovation and on the resources of small medical device manufacturers (which typified the industry in 1976 and still do today). See MDMA Br. 4-7; HIMA Br. 22-29; Ctr. for Patient Adv. Br. 11-23. And the best possible evidence that Congress *did* act on these concerns is the words of the statute.[3]

Furthermore, it certainly is not unusual for Congress to protect the public with comprehensive federal regulation on the one hand while preempting state tort remedies on the other. See, e.g., *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992); *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658 (1993).[4] And this

---

[3] The presence of an exemption clause (21 U.S.C. 360k(b)) allowing states to supplement federal regulation, *but only when the FDA agrees that the supplemental regulation meets certain standards*, mitigates any possible harshness from the breadth of the basic preemption provision (*id.* § 360k(a)). Cf. Cal. Br. 15-17 (asserting that, under a broad reading of the preemption provision, a "state remains powerless" to protect its own citizens, but *completely ignoring* exemption provision).

[4] This Court's decision in *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238 (1984), does not warrant a different conclusion. As the opinion makes clear, *id.* at 249-256, and as the Court subsequently has explained, "the decision in *Silkwood* was based in substantial part on legislative history suggesting that Congress did not intend to include in the pre-empted field state tort remedies for radiation-based injuries." *English* v. *General Elec. Co.*, 496 U.S. 72, 86 (1990). Equally inapposite is *United Constr. Workers* v. *Laburnum Constr. Corp.*, 347 U.S. 656 (1954). See Nat'l Conf. of State Legis. Br. 6, 27-28; TLPJ Br. 16-17; ATLA Br. 14, 24; PLC-MDL Br. 5-6, 19. This Court's resolution of the question presented in *Laburnum*—whether Congress's

(Footnote continued on next page)

Court often has found preemption "even when the state action purported to authorize a remedy unavailable under the federal provision." *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 55 (1987). At least since *San Diego Building Trades Council* v. *Garmon*, 359 U.S. 236 (1959), the law has been settled that "the States' salutary effort to redress private wrongs or grant compensation for past harm" cannot justify state intrusion into a federal regulatory system, even though "the state remedy ha[s] no federal counterpart." *Id.* at 247; see also *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 584 (1981) ("A finding that federal law provides a shield for the challenged conduct will almost always leave the state-law violation unredressed."); *Gillespie* v. *United States Steel Corp.*, 379 U.S. 148, 154-155 (1964) (Jones Act preempts state law even though plaintiff had no cause of action under the Act).[5]

(Footnote continued from previous page)
assignment to the NLRB of exclusive jurisdiction over unfair labor practices precluded a common law damages action arising out of conduct that might qualify as such an unfair practice—rested on numerous factors that simply have no application to this case. See 347 U.S. at 664-669 (relying *inter alia* on "the language of the Act," its "legislative history" and prior decisions interpreting the statute as "leav[ing] much to the states.")

[5] In any event, contrary to plaintiffs' assertions, Congress *did* provide a federal remedy to compensate consumers for devices that present an unreasonable health risk because they were not properly designed or manufactured. The statute gives the FDA authority to issue orders requiring device manufacturers to repair the device, replace it with one that conforms to FDCA requirements, or refund its purchase price. This federal remedy also includes "any reasonable and foreseeable expenses." 21 U.S.C. 360h(b)(3). If the FDA does not issue the order on its own initiative, any affected person may petition the agency to take action. 21 C.F.R. 10.25, 10.30. Although the statutory remedy is more limited than tort recovery might offer, the provision of reasonable and foreseeable expenses could include the types of medical expenses that Mrs. Lohr alleges she incurred in this case. Thus, plaintiffs are wrong in asserting that preemption of their tort claims would deny them access to any remedy for a defective device.

Whatever policies and "presumptions" the parties and amici may advance,[6] in the end this case must turn on the plain wording of the statute, which "necessarily contains the best evidence of Congress' pre-emptive intent," *Easterwood*, 507 U.S. at 664. As we now show, the statutory language, as informed by this Court's decisions, demonstrates that the FDCA preempts plaintiffs' claims for failure to warn and defective manufacture.

SUMMARY OF ARGUMENT

I. Under this Court's opinion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), common law damages actions establish state "requirements" subject to preemption under the MDA. Plaintiffs attempt to distinguish *Cipollone*, but ultimately they merely re-argue issues the Court already has resolved against them.

The language of the FDCA preemption provision encompasses state common law claims. The Court should reject—as the Solicitor General does—plaintiffs' argument that the use of the term "requirement" three times in the preemption provision preserves common law claims. Although modifiers indicate that the two references to federal requirements only concern positive law, there are no similar modifiers that limit state requirements to positive law. The statutory language also does not support plaintiffs' argument restricting preemption only to those state requirements that apply exclusively to devices.

In addition, the Court should reject—again, as the Solicitor General does—plaintiffs' argument that common law claims are not subject to the statutory exemption provision, and therefore are outside the scope of the preemption provision. The exemption provision does cover common law claims. Even if it did not, there is no basis in the statute for concluding that the ab-

---

[6] Compare Nat'l Conf. of State Legis. Br. 6-7 (strong presumption against preemption) with GM Br. 19-23 (no presumption against preemption except in cases of "field" preemption).

sence of an exemption affects the scope of preemption under the statute. Furthermore, the limited "savings clause" set forth at 21 U.S.C. 360h(d) does not contemplate preservation of tort claims, because it easily can be read to refer to other types of state-law liability.

II. The FDCA preempts plaintiffs' failure-to-warn claims. The FDCA establishes significant federal requirements governing product warnings through the 510(k) process, the prescription device labeling regulation, post-market warning requirements, and the FDCA's general misbranding provisions. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of the FDCA preemption provision. The Court should reject plaintiffs' argument that these requirements are not preemptive because they are not "device-specific"; plaintiffs' construction has no basis in the statutory language.

Plaintiffs' claims for failure to warn are preempted because they would establish state duties "different from, or in addition to," the federal prescription device labeling regulation, the 510(k) requirements, and the general misbranding provisions of the FDCA. The premise of these claims is that warnings that comply with these federal requirements are inadequate, and that state common law requires different and additional warnings. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that fact alone is enough to preempt them.

III. The FDCA also preempts plaintiffs' defective manufacturing claims. The FDA's Good Manufacturing Practice ("GMP") regulations and the 510(k) process impose significant federal manufacturing requirements. These requirements have preemptive effect, because they are "applicable to the device" within the meaning of Section 360k(a).

Plaintiffs' claims are preempted because they would establish state duties "different from, or in addition to," the GMP regulations and 510(k) requirements. The premise of these

claims is that a manufacturing process that complies with these federal requirements is inadequate, and that state common law requires a different process. In addition, the state duties that would be imposed by plaintiffs' claims are not the same as the standards imposed by the federal requirements, and that is enough to preempt the claims.

IV. The FDCA also preempts plaintiffs' claims to the extent that they rely on federal standards. According to plaintiffs, identical state and federal requirements are not "different from, or in addition to," each other. That interpretation, however, is flawed: it reads the statute as if it preempts only "different" state requirements, and thus renders completely superfluous the phrase "in addition to." Moreover, plaintiffs' interpretation is inconsistent with the structure and legislative history of the MDA and the congressional intent to establish uniform device requirements. Equally mistaken is the Solicitor General's submission that "remedies" do not constitute "requirements." Contrary to the government's assertion, the FDA has *not* "consistently, and reasonably" (U.S. Br. 9-10) read the term "requirement" to exclude remedies. In fact, the FDA on several occasions has indicated that "remedies" *are* a species of state "requirements."

ARGUMENT

The first and longest argument in plaintiffs' opening brief (Cross-Pet. Br. 14-34)—which also is the *sole* argument made by most of plaintiffs' amici—is a sweeping assertion that the FDCA preempts *no common law damages claims at all*. The Solicitor General disagrees, as do the FDA and nine courts of appeals. U.S. Br. 15-19 & n.12; Pet. Br. 37 n.19.[7] We show in Point I below that both this Court's *Cipollone* decision and the language and structure of the statute foreclose plaintiffs'

---

[7] One court of appeals agrees with plaintiffs. *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) (Ferguson, J.); see also *id.* at 1460-1462 (Reinhardt, J., concurring).

argument. Plaintiffs' next argument is that the common law claims preempted by the FDCA do not include the failure-to-warn and defective manufacturing claims in *this* case. Cross-Pet. Br. 34-45. We show in Points II (failure to warn) and III (defective manufacturing) that plaintiffs are wrong; the court of appeals correctly held these claims preempted.

Finally, plaintiffs argue briefly that they may escape preemption by recasting their state-law claims as claims relying on federal standards. Cross-Pet. Br. 45-47. A cryptic passage in the Solicitor General's brief likewise claims that the FDA has consistently interpreted the term "requirement" in Section 521(a) not to preempt state tort remedies—even though that interpretation was newly conceived for this case. We show in Point IV below that acceptance of these arguments would be inconsistent with Congress's carefully crafted remedial scheme and the language and purpose of the statute.[8]

I. COMMON LAW CLAIMS ESTABLISH STATE REQUIREMENTS SUBJECT TO PREEMPTION UNDER THE FDCA

A. This Court Should Reject Plaintiffs' Re-Argument of Issues Resolved in *Cipollone*

Medtronic's opening brief explains that under the holding in *Cipollone*, 505 U.S. 504 (1992), plaintiffs' claims would establish state "requirements" within the meaning of the FDCA preemption provision. See Pet. Br. 36-39. Plaintiffs understandably seek to distinguish *Cipollone*, but, as the Solicitor General

---

[8] Plaintiffs and their amici rely extensively on a recent law review article that argues that the FDCA does not preempt common law claims. See Robert S. Adler & Richard A. Mann, *Preemption & Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895 (1994). For a point-by-point response to that article, see Mark Herrmann & Geoffrey J. Ritts, *Preemption & Medical Devices: A Response To Adler & Mann*, 51 Food & Drug L.J. 1, 8-19 (1996) (page proof copies of which have been lodged with the Clerk).

explains, their arguments are "difficult to square with" that decision. U.S. Br. 15-19.

Plaintiffs assert that common law claims merely require manufacturers to compensate plaintiffs and "do not require manufacturers to take any action with respect to a device." Cross-Pet. Br. 20; see also ATLA Br. 5-10. That assertion contradicts the fundamental premise of the *Cipollone* holding, which is that common law regulates conduct in the same manner as statutes or regulations. As Justice Stevens explained in his plurality opinion, common law claims establish state "requirements" because "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 505 U.S. at 521 (quoting *Garmon*, 359 U.S. at 247).[9]

Cipollone also disposes of plaintiffs' argument that there can be no preemption of their claims without an explicit statutory reference to extinguishment of tort remedies, Cross-Pet. Br. 18, 31. The Cigarette Act at issue in *Cipollone* contained no explicit reference to common law claims, yet the Court affirmed their preemption. See also *Easterwood*, 507 U.S. at 664 (affirming preemption of common law claims without explicit reference to such claims in express preemption provision).

Cipollone further forecloses plaintiffs' argument that their claims are preserved because they are not "establish[ed] or continue[d] in effect" by a state, Cross-Pet. Br. 21-22. There is no principled distinction between the terms of the FDCA and the language of the Cigarette Act at issue in *Cipollone*, which pre-

---

[9] The Court's analysis in *Cipollone* was consistent with earlier cases recognizing that exposure to common law claims compels manufacturers to change their conduct to avoid future liability. See, e.g., *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 495 (1987); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981).

empted requirements "imposed" under state law, *Cipollone*, 505 U.S. at 515. Similarly, this Court held in *Easterwood* that common law claims were preempted under a Federal Railroad Safety Act provision barring "[a] State" from "adopt[ing] or continu[ing] in force" certain railroad safety standards. 507 U.S. at 662 & n.2.

Finally, *Cipollone* rejects plaintiffs' assertion that the statute preserves their claims because its legislative history does not explicitly refer to preemption of tort actions, Cross-Pet. Br. 30.[10] In *Cipollone*, this Court affirmed preemption of common law personal injury claims, even though portions of the Cigarette Act's legislative history suggested that "Congress was primarily concerned with positive enactments by States and localities," 505 U.S. at 521 (opinion of Stevens, J.), and there was no explicit reference in the legislative history to common law damages actions, *id.* at 540 (opinion of Blackmun, J.). Because the Act's *language* "plainly reache[d] beyond" positive enactments, 505 U.S. at 521 (opinion of Stevens, J.), the Court held that common law claims were subject to preemption. Similarly, in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 385 n.2 (1992), this Court held that the Airline Deregulation Act preempted state advertising standards, even though the statute's legislative history contained no statements specifically ad-

---

[10] There is no claim that the legislative history contains statements *negating* the conclusion that tort actions are preempted. Instead, plaintiffs explicitly rely on "[t]he legislative history's *silence* on preemption of damages remedies." Cross-Pet. Br. 30 (emphasis added). Some of plaintiffs' amici do purport to find evidence in individual legislators' statements or in committee reports that the FDCA does not preempt tort claims (e.g., TLPJ Br. 7-8 & nn.5-6; AARP Br. 4 n.1, 19 n.10), but they rely on materials associated with *subsequent* legislation, or even subsequent congressional inaction. Such materials have no probative value at all. See *Brown* v. *Gardner*, 115 S. Ct. 552, 557 (1994); *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 114 S. Ct. 1439, 1453 (1994); *Pension Benefit Guaranty Corp.* v. *LTV Corp.*, 496 U.S. 633, 650 (1990); *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 175 n.1 (1989).

dressing state regulation of advertising. See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n.2 (1990) (statute can have effects not explicitly mentioned in its legislative history). In the present case, the Court also should conclude that the statutory language mandates preemption despite the silence of the legislative history.

B. The Language of the FDCA Preemption Provision Encompasses Common Law Claims

1. The Preemption Provision's Use of the Term "Requirement" Three Times Does Not Exclude State Common Law Claims

Plaintiffs contend that the term "requirement" in the FDCA preemption provision necessarily means the same thing each of the three times it appears. Because two of the three references are to federal requirements imposed solely pursuant to statute or regulation, plaintiffs argue that the single reference to state requirements is similarly limited, excluding common law claims. Cross-Pet. Br. 18-19. As the Solicitor General explains, plaintiffs' argument does not withstand scrutiny. U.S. Br. 17.

Like the Cigarette Act in *Cipollone*, the FDCA defines pre-empted state requirements according to their content and does not distinguish between common law and positive enactments. See *Cipollone*, 505 U.S. at 515. State requirements are pre-empted if they "*relate*[] [i] *to the safety or effectiveness of the device or* [ii] *to any other matter included in a requirement applicable to the device*" under the FDCA and fit the other terms of the preemption provision. 21 U.S.C. 360k(a)(2) (emphasis added). In contrast, the FDCA defines preemptive *federal* requirements with modifiers indicating their statutory and regulatory *source* rather than their subject matter. Thus, the FDCA describes a preemptive requirement as "*any requirement applicable under this chapter to the device.*" *Id.* § 360k(a)(1) (emphasis added). As the Solicitor General notes, the obvious conclusion that federal requirements derive from regulations and statutory provisions rather than common law does not extend to

the state requirements, because the FDCA does not limit state requirements with any modifier referring to positive law. U.S. Br. 17; see also Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 8-9.

Finally, plaintiffs' construction of the FDCA preemption provision would lead to absurd results. Their distinction between common law and positive law is particularly untenable in a state like Florida, which has adopted common law doctrines *by statute*.[11] Furthermore, if preempted state requirements were limited to positive law, the FDCA would prohibit personal injury claims in states that have codified their tort doctrines[12] but preserve claims in states that have not. Plaintiffs' construction of the statute would establish an irrational pattern of liability exposure from state to state, undermining the congressional intent to establish uniform nationwide requirements for medical devices. See Pet. Br. 4-5. This Court should conclude that the FDCA's language does not support plaintiffs' untenable distinction between common law and positive law.

2. The FDCA Does Not Restrict Preemption to State Requirements That Apply Exclusively to Devices

Relying on an FDA regulation, plaintiffs assert that Section 360k(a) does not apply to common law claims because it pro-

---

[11] See, e.g., *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) ("In 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute, in modified form but unchanged as to substance, is still in effect * * *.") (Boyd, C.J., dissenting), cert. denied, 479 U.S. 1065 (1987).

[12] See, e.g., Conn. Gen. Stat. Ann. §§ 52-572m to 52-572q (West 1991); Ind. Code Ann. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); La. Rev. Stat. Ann. §§ 9:2800.51 to 9:2800.59 (West 1991); Me. Rev. Stat. Ann. tit. 14, § 221 (West 1980); Miss. Code Ann. § 11-1-63 (Supp. 1994); Mont. Code Ann. § 27-1-719 (1993); N.C. Gen. Stat. §§ 99B-1 to 99B-11 (Michie 1995); Ohio Rev. Code Ann. §§ 2307.71 to 2307.80 (Baldwin 1996); S.C. Code Ann. §§ 15-73-10 to 15-73-30 (Law. Co-op. 1993).

hibits only those state requirements that apply exclusively to devices. Cross-Pet. Br. 19-21. As the Solicitor General explains, however, plaintiffs' argument is "strained as a grammatical matter," because the statutory language encompasses state requirements "of general applicability" such as tort duties. U.S. Br. 17-18. The Solicitor General's brief, in fact, flatly contradicts the FDA's previous interpretation. Compare U.S. Br. 18 (the language of the preemption provision "suggests that such a [preempted state] 'requirement' may be one *of general applicability*") (emphasis added) with 21 C.F.R. 808.1(d)(1) ("Section 521(a) does not preempt State or local requirements *of general applicability* where the purpose of the requirement relates * * * to *other products in addition to devices* * * *.") (emphasis added).[13]

Plaintiffs argue that claims asserting violations of generally applicable tort duties are not preempted because, under the statute, "only state *requirements* '*with respect to a device*' are candidates for preemption." Cross-Pet. Br. 19-20 (emphasis added). But plaintiffs' construction changes the order of words in the statutory language, thereby altering their meaning. Section 360k(a) provides that state requirements may not be "*establish[ed] or continue[d] in effect with respect to a device*" (emphasis added). Thus, the phrase "with respect to a device" modifies the verbs "establish" and "continue in effect" rather than the noun "requirement." As the Solicitor General notes, the statutory language indicates that the requirements could be established or continued in effect in other contexts not involving

---

[13] The Solicitor General's abandonment of the FDA's gloss on the statute wisely anticipated this Court's decision in *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), which points out (slip op. 15) that "a statute may specifically relate to more than one thing" and that Congress's preemptive intent is not to be disregarded just because a statute relates to other things in addition to the subject cited in the statute.

devices; requirements therefore need not apply exclusively to devices to be preempted. U.S. Br. 18.[14]

Plaintiffs' interpretation also would "creat[e] an utterly irrational loophole." *Morales*, 504 U.S. at 386. For example, under their interpretation, the FDCA would preserve a general state product warning or manufacturing requirement not directed exclusively to devices, even if it directly conflicted with federal device warning or manufacturing requirements. But, as this Court noted in *Morales*, "there is little reason why state impairment of the federal scheme should be deemed acceptable so long as it is effected by the particularized application of a general statute." *Ibid.* Plaintiffs' construction also would allow states to avoid preemption by the simple expedient of structuring their medical device statutes and regulations to apply to one or two other products (e.g., drugs) in addition to devices. Plaintiffs fail to explain why Congress would have wanted a regime that tolerates such conflicting state regulation and permits such easy circumvention of the preemption clause.[15] See also PLAC Br. 16-20.

---

[14] See also *Cipollone*, 505 U.S. at 515 (affirming preemption of claims under generally applicable common law doctrines as requirements *imposed* under state law *with respect to* the advertising or promotion of any cigarettes); *American Airlines, Inc.* v. *Wolens*, 115 S. Ct. 817, 821 (1995) (affirming preemption of claims under generally applicable consumer fraud statute as state law *relating to* rates, routes, or services of any air carrier); *Morales*, 504 U.S. at 386 (preempting application of general consumer protection statutes to air carrier advertising).

[15] The Court should reject plaintiffs' assertion that it should defer to the agency pronouncements they cite to support their construction of the statute. Deference to agency interpretations is not appropriate in cases such as this, in which the intent of Congress is clear in the statute. *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984). Furthermore, the Solicitor General has resolved any doubt about the propriety of deference by abandoning the pronouncements cited by plaintiffs. The Solicitor General agrees with Medtronic that generally applicable common

(Footnote continued on next page)

C. Other Provisions of the FDCA Support Preemption of Common Law Claims

Citing 21 U.S.C. 360k(b), which grants the FDA authority to exempt state requirements from preemption, plaintiffs argue that Congress could not have intended the exemption provision to apply to state requirements established through common law claims, because it is not practically feasible to grant exemptions for such requirements. They further reason that, if the exemption provision in subsection (b) does not encompass common law claims, neither does the preemption provision in subsection (a). Cross-Pet. Br. 24-27. As the Solicitor General explains, however, plaintiffs' assumption and conclusion are both invalid. See U.S. Br. 18-19.

Congress said nothing in subsection (b) to exclude common law duties. Medtronic agrees that it might be very difficult for a state to demonstrate that its common law duties meet the standards of subsection (b) and warrant an exemption. But that *practical* difficulty does not exclude common law duties from the broad statutory language. See U.S. Br. 18.[16]

Furthermore, even if subsection (b) excluded common law claims entirely, as plaintiffs suggest, there is nothing in the statute indicating that Congress intended to ensure the availability of an exemption for every type of requirement subject to preemption under subsection (a). As the Solicitor General notes, Congress may well have contemplated that the difficulties of granting an exemption for common law requirements exclude

---

(Footnote continued from previous page)
law duties are preempted if they are different from, or in addition to, applicable FDCA requirements. U.S. Br. 10-12, 15-19.

[16] It may be relatively rare for a state to apply for an exemption for common law doctrines, as plaintiffs note. Cross-Pet. Br. 24-27. Nonetheless, the FDA has never taken the position that exemptions for common law duties are unavailable, "and the FDA does not do so here." U.S. Br. 18 n.13.

them from subsection (b), even though they are subject to pre-emption under subsection (a). U.S. Br. 18-19.[17]

The Court also should reject plaintiffs' argument that 21 U.S.C. 360h contemplates preservation of tort claims against device manufacturers. See Cross-Pet. Br. 27-28. That section gives the FDA broad authority to issue administrative orders to remedy unreasonable public health risks created by medical devices. Section 360h(d) also states that compliance with one of these remedial orders does not affect other liability under state or federal law:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

This reference to federal or state liability is not necessarily a reference to personal injury tort claims, and a general reference to "liability" certainly does not indicate that all tort claims are beyond the reach of the preemption provision. Section 360h(d)

---

[17] Congress's desire not to hamper the innovation of life-saving medical technologies, or to burden unduly the small manufacturers that make up this industry, is manifest in the overall design and structure of Section 360k, which includes both a very broad preemption provision and an exemption provision that grants discretion to the expert federal regulator to make exceptions if certain statutory criteria are satisfied. That design largely removes the onus from manufacturers to determine which state requirements are preempted, and places the burden instead on states to seek exemptions in cases of doubt. That structure also permits a single national decisionmaker—the FDA—to assess the incremental effect of multiple or successive exemptions on the cost and availability of particular devices. And it vests in the expert agency the authority—at least when the statutory criteria for an exemption are satisfied—to assess a state's assertions about the need for "different" or "addition[al]" safety and effectiveness requirements, as well as to weigh the benefits of such requirements against the burdens they would impose.

can easily be read as having nothing to do with tort liability, referring instead to state contractual liability for economic loss in disputes between device manufacturers, importers, distributors, and retailers arising from issuance of an agency remedial order.[18] The clause also could apply to state tort duties (whether or not codified by statute) that the FDA exempts from preemption. See pp. 16-17 *supra*. These readings of the statute respect the broad language of the FDCA preemption provision, consistent with this Court's decisions establishing that savings clauses "cannot in reason be construed as continuing * * * a common law right, the continued existence of which would be absolutely inconsistent with the provisions of [an] act." *Texas & Pac. Ry.* v. *Abilene Cotton Oil Co.*, 204 U.S. 426, 446 (1907); see also *Morales*, 504 U.S. at 384-385; GM Br. 16-17; Herrmann & Ritts, *supra*, 51 Food & Drug L.J. at 10-12.

II. THE FDCA PREEMPTS PLAINTIFFS' FAILURE-TO-WARN CLAIMS

Relying on different rationales, plaintiffs, their amici, and the Solicitor General all argue that, even if state "requirements" covered by Section 360k(a) can include common law claims, the failure-to-warn and defective manufacturing claims in this case are not preempted. Plaintiffs and their amici rest almost entirely on the notion (founded in an FDA regulation and *not* in the statute itself) that only "device-specific and subject-specific" federal requirements have any preemptive effect. Cross-Pet. Br. 39-44; see Calif. Br. 11-17; PLC-MDL Br. 7-14. The Solicitor General *rejects* that argument (U.S. Br. 18) but presents rea-

---

[18] For example, if the FDA orders a wholesale distributor to repair a retailer's shipment of defective devices under Section 360h(b), the retailer may still wish to sue the distributor for breach of contract. Section 360h(d) would allow the suit to proceed, with the value of the repaired devices being subtracted from any additional damages recovered. Cf. *Wolens*, 115 S. Ct. at 826 (claims under Illinois Consumer Fraud Act preempted, but savings clause preserved contractual remedies).

sons—which are rather opaque—why he believes plaintiffs' claims survive preemption nevertheless. U.S. Br. 22-28.

The reason for this disarray of rationales is not hard to fathom. Plaintiffs, their amici, and the Solicitor General are not willing to focus on the one sure guide to statutory interpretation: the words that Congress enacted. Attention to those simple words makes it quite easy to apply the preemption provision to this case—and to conclude that plaintiffs' claims are preempted.

The FDCA preemption provision is written in the following broad words:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, *any requirement applicable under this chapter to the device*, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a) (emphasis added). It is beyond rational debate—although both plaintiffs (Cross-Pet. Br. 34-38) and the Solicitor General (U.S. Br. 19-21, 22 n.16) continue to debate the point—that *any* FDCA requirement applicable to the device has preemptive effect. Thus, when the Solicitor General asserts that the 510(k) process has no preemptive effect at all because it "does not reflect a determination by the FDA that the device is safe and effective, much less a specific determination that the device's design is required to ensure its safety and effectiveness," U.S. Br. 19, he answers a question that the statute does not ask.[19] This Court is not called upon to decide how far the

---

[19] "No answer is what the wrong question begets * * *." Alexander Bickel, *The Least Dangerous Branch* 103 (1962). The Eleventh Circuit made

(Footnote continued on next page)

510(k) process goes to ensure safety and effectiveness, but rather only whether it imposes a "requirement applicable under this chapter to the device."[20] And there is no possible doubt that it does, for reasons explained in our opening brief (Pet. Br. 30-36).[21]

The 510(k) requirements are not the only federal requirements that apply to the Model 4011 with preemptive effect. As we will now explain in detail, *several* federal "requirements" are preemptive, and plaintiffs' claims would establish state requirements that are "different from, or in addition to," those federal requirements and that relate to safety and effectiveness and other matters covered by the FDCA.

(Footnote continued from previous page)
the same error (Pet. App. 26a-27a), although it correctly held that plaintiffs' failure-to-warn and defective manufacturing claims are preempted.

[20] Even the preempted *state* requirement need only "relate[] to" safety or effectiveness (or another matter included in an applicable FDCA requirement). 21 U.S.C. 360k(a)(2). Congress did not apply even *that* modest limitation (see *Barnett Bank*, slip op. 12) to the *federal* requirement. See *id.* § 360k(a)(1). There is no textual basis for the Solicitor General's bold assertion that a preemptive federal requirement must not only relate to, but also *ensure*, safety and effectiveness. In any event, as Medtronic explained in its opening brief, the 510(k) process *does* impose significant safety and effectiveness requirements on the Model 4011. See Pet. Br. 19-30.

[21] The Solicitor General *himself* recognizes that anything referred to in other sections of the FDCA as a "requirement" must be a requirement for purposes of Section 360k(a), yet he ignores the logical consequence of that argument, which is that requirements imposed under the 510(k) process must be preemptive. Compare U.S. Br. 24 n.19 (conceding "that the GMPs impose 'requirement[s]' within the meaning of Section [360k](a)" because other sections of the FDCA refer to them as imposing "requirements") with Pet. Br. 31-32 (arguing, in a passage that the Solicitor General ignores, that Section 510(k) imposes "requirements" within the meaning of Section 360k(a) because other sections of the FDCA refer to it as imposing "requirements").

A. The FDCA Establishes Substantial Requirements for Product Warnings Concerning the Model 4011

1. The 510(k) Process Imposes Substantial Requirements Concerning Labeling Warnings

The 510(k) premarket clearance process imposes substantial requirements concerning labeling warnings for prescription devices such as the Model 4011.[22] It prevents marketing without FDA clearance, requires submission of significant information about the device for FDA review, and bars significant changes without further FDA clearance. See Pet. Br. 19-30. All of these requirements apply with full force to the Model 4011's labeling.[23]

Manufacturers must submit proposed labeling for agency review to obtain 510(k) clearance. 21 C.F.R. 807.87(e).[24] The FDA reviews the labeling as part of its determination of sub-

---

[22] The FDCA distinguishes the term "label" from the broader term "labeling." "Label" means "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. 321(k). "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). Under the FDCA, "labeling" includes a broad variety of product literature (including technical manuals explaining product use and promotional materials), even if they do not physically accompany distribution of the device. See *Kordel* v. *United States*, 335 U.S. 345 (1948).

[23] Plaintiffs fail to mention most of these requirements and incorrectly characterize the 510(k) process as a notification provision. See Cross-Pet. Br. 5, 34-35.

[24] Plaintiffs cite a GAO report for the proposition that the FDA may clear devices for marketing without submission of labeling. Cross-Pet. Br. 42. The report does not support plaintiffs' assertion, because it indicates only that some 510(k) applications lack labeling when the FDA initially *receives* them. U.S. General Accounting Office, Medical Devices: FDA's 510(k) Operations Could Be Improved 62 (GAO/PEMD-88-14, Aug. 1988). The FDA's authority to ask for additional information before granting premarket clearance (see 21 C.F.R. 807.87(k)) resolves such deficiencies. In any event, Medtronic did submit labeling in its 510(k) application concerning the Model 4011.

stantial equivalence. See, e.g., FDA Draft Guidance for Format and Content for Premarket Notification 510(k) (Mar. 23, 1994) at A-8, A-13 ("Substantial equivalence is to be established with respect to, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, *labeling*, and other applicable characteristics.") (emphasis added). For devices in which the inclusion of specific warnings is critical to a finding of substantial equivalence, the FDA's review "includes an evaluation of the compliance of the proposed labeling, or portions thereof, with applicable requirements under 21 C.F.R. Part[] 801." Device Labeling Guidance, FDA General Prog Memorandum #G91-1 (Mar. 8, 1991) at 2. The 510(k) review also may lead the agency to *prohibit* certain warnings that it deems inappropriate. See, e.g., FDA 510(k) Clearance Letter K914966 (May 13, 1992) (barring warnings regarding use of bone screw in the spine).

After marketing begins, the 510(k) requirements also bar manufacturers from changing labeling warnings in a manner that could affect safety or effectiveness of the device significantly unless the FDA clears the labeling changes through another 510(k) review. See 21 C.F.R. 807.81(a)(3)(i). For example, 510(k) review is required for labeling changes that arise from significant new issues of safety or effectiveness not evident at the time of initial FDA clearance. If the manufacturer makes significant labeling changes without FDA clearance, the agency may initiate an enforcement action to stop distribution of the device. Cf. Complaint, *United States* v. *11,307 Boxes*, No. 93-574 (S.D. Fla. filed Mar. 24, 1993) (seizure complaint alleging significant changes of labeling in violation of 21 C.F.R. 807.81(a)(3)).

2. The Prescription Device Labeling Regulation Imposes Substantial Warning Requirements

The FDA's prescription device labeling regulation, 21 C.F.R. 801.109, imposes substantial requirements on the Model 4011, contrary to plaintiffs' suggestion that it does "little more

than tell manufacturers to list * * * warnings * * * and the like." Cross-Pet. Br. 43. The regulation requires that the labeling disclose information concerning use of the prescription device, "including indications, effects, routes, methods, and frequency and duration of administration." 21 C.F.R. 801.109(c). In addition, the regulation requires the manufacturer to include the following warnings on the labeling so that physicians are adequately informed of

> any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

Ibid. The regulation does, however, allow manufacturers to omit those directions, hazards, and warnings that are "commonly known to practitioners licensed by law to use the device." *Ibid.*

Furthermore, under the regulation, devices such as the Model 4011 may be sold "only to or on the prescription or other order of [a] practitioner for use in the course of his professional practice." 21 C.F.R. 801.109(a)(2); R1-37-Exh.1, at 3-4. By definition, prescription devices are those for which there cannot be adequate directions for use by laypersons. 21 C.F.R. 801.109. To ensure appropriate physician oversight, the regulation requires manufacturers to include a legend restricting the device "to sale by or on the order of a physician." 21 C.F.R. 801.109(b)(1); R1-37-Exh.1, at 3.

The FDA's enforcement activities underscore the significance of these requirements. As the Eleventh Circuit noted, "the FDA's record of taking action against mislabeled devices forecloses the argument that the Act's labeling requirements lack substantive 'bite.' " Pet. App. 33a.; see, e.g., *United States* v. *An Article of Device*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) (seizure action for violation of 21 C.F.R. 801.109); *United States* v. *Articles of Device*, 426 F. Supp. 366 (W.D. Pa. 1977) (same).

3. The FDCA and Related Regulations Give the FDA Substantial Authority to Require Additional Warnings After Marketing Begins and Prohibit Distribution of Devices with Inadequate Warnings

Although the FDA has not required warnings for the Model 4011 beyond those in the labeling cleared through the 510(k) process, the agency does have substantial authority to require additional warnings once marketing begins. Under 21 C.F.R. 895.25, the FDA may require manufacturers to change a device's labeling to contain statements, notices, or warnings if the device presents unreasonable public health risks. 21 C.F.R. 895.25(a), (b). The FDA has authority to dictate when the labeling change must occur and how long it must last. *Id.* § 895.25(a)(3), (b). If the manufacturer does not carry out the required change in labeling, the FDA has authority to initiate a proceeding to ban the device, 21 U.S.C. 360f; 21 C.F.R. 895.25(d), or take the device off the market through its other broad remedial powers. See, e.g., 21 U.S.C. 360h(e) (cease and desist authority), 334 (seizure authority). The FDA also has power to require manufacturers to issue notifications (separate and apart from any labeling) warning the public about significant health risks it detects through a variety of sources, including manufacturers' mandatory reports of device malfunctions, serious injuries, and deaths. See 21 U.S.C. 360h(a), (e), 360i.

The FDCA also establishes general prohibitions on distribution of devices rendered unsafe by inadequate warnings. A device is "misbranded" under the statute if the warnings in its labeling are not adequate such that the device may be dangerous to health or if use in accordance with the labeling renders it dangerous to health. 21 U.S.C. 352(f)(2), 352(j). A device also is misbranded if its labeling is "false or misleading" because it omits material warnings. 21 U.S.C. 352(a), 321(n). Manufacturers of misbranded devices are subject to criminal prosecution and actions for seizure, injunction, and civil penalties, among other sanctions. See *id.* §§ 331-334.

B. The Federal Warning Requirements Have Preemptive Effect Because They Are "Applicable to the Device"

"[A]ny requirement applicable under [the FDCA] to the device" has preemptive effect. 21 U.S.C. 360k(a)(1). The plain meaning of that language encompasses all of the federal warning requirements described above. In addition, two other sections characterize the 510(k) requirements as "appl[icable] to the device" (see Pet. Br. 30-32). One of those other sections also characterizes the prescription device labeling regulation and general misbranding provisions as federal requirements "appl[icable] to the device." 21 U.S.C. 360j(a).[25] These federal requirements are therefore preemptive.

Rather than analyzing whether the federal warning requirements are "applicable to the device," as the statute mandates, plaintiffs examine whether they apply *exclusively* to a *single* type of device; under plaintiffs' construction of the statute, only "device-specific" requirements are preemptive. Cross-Pet. Br. 39-42; see also, e.g., Calif. Br. 11-17; PLC-MDL Br. 7-14. But nothing in the language of the preemption provision limits the phrase "any requirement applicable under [the FDCA] to the device" to those requirements that apply exclusively to a single type of device. The court of appeals correctly held that the language of Section 360k(a) "does not suggest that the requirements themselves must mention the particular device in question" in order to have preemptive effect. Pet. App. 19a.[26]

---

[25] Section 360j(a) unequivocally establishes that the requirements of Section 502 of the FDCA are applicable to the device unless the FDA changes their applicability or other statutory provisions not relevant to this case conflict with them. The general misbranding provisions are set forth in Section 502 of the FDCA, 21 U.S.C. 352, and the prescription device labeling regulation was promulgated under FDCA § 502(f)(1), 21 U.S.C. 352(f)(1). See 21 C.F.R. 801.109.

[26] Plaintiffs cite the Fifth Circuit's decision in *Moore* v. *Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), for the proposition that federal

(Footnote continued on next page)

Furthermore, plaintiffs' construction of the preemption provision is inconsistent with the congressional intent to enact a "general prohibition on non-Federal regulation." H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). If preemption were limited to device-specific federal requirements, relatively trivial conflicts between federal and state law (relating only to a single device) would be prohibited, while the statute would leave intact significant broad-based conflicts (relating to numerous devices). For example, federal warning requirements uniquely applicable to pacemaker leads would preempt state regulations imposing different warning requirements, yet federal warning requirements governing broad categories of devices would not preempt similarly broad state laws. Indeed, because there are fewer than two dozen substantive device-specific FDA regulations, and only one device-specific requirement in the statute, plaintiffs' interpretation would wholly eviscerate the FDCA preemption provision.

In addition, plaintiffs' interpretation would make preemption turn on whether the applicable federal regulation explicitly refers to the device at issue—an absurd result with no support in the statutory language. Plaintiffs' interpretation would severely handicap the FDA in promulgating a preemptive regulation, which would need to list every device to which it applied, even if it affected thousands of devices.

Lacking support for their position in the statutory language, plaintiffs retreat to FDA interpretations to justify their construction of the FDCA preemption provision. But the Solicitor General indicates that federal requirements *need not* be device-

---

(Footnote continued from previous page)
requirements do not preempt state law unless they are device-specific. See Cross-Pet. Br. 14, 31, 43. But the Fifth Circuit has rejected the *Moore* holding, stating that, "since *Moore*, it has become clear that these regulations need *not be device-specific*; they need only apply generally to the device at issue" to preempt state law. *Feldt* v. *Mentor Corp.*, 61 F.3d 431, 436 (5th Cir. 1995) (emphasis added).

specific to be preemptive. The Solicitor General's brief does not even *refer to* the agency interpretations that are the premise for plaintiffs' argument and concedes that the GMP regulations, which apply to thousands of devices, are federal "requirements" under the FDCA preemption provision. See U.S. Br. 24 n.19, 25 n.20.

Although the Solicitor General correctly refutes plaintiffs' analysis, he nonetheless joins their conclusion that there are no preemptive federal requirements applicable to plaintiffs' failure-to-warn claim. U.S. Br. 27-28. The Solicitor General asserts that the 510(k) requirements are not preemptive because they do not reflect a "determination" that the device is safe and effective or an "approval" of the adequacy of the device's labeling (U.S. Br. 19-20, 28). As we have explained (pp. 19-20, *supra*), however, that approach lacks *any* basis in statutory text. And the Solicitor General is silent on the question whether the general misbranding provisions of the FDCA are federal "requirements" within the meaning of Section 360k(a), and he does not even refer to the prescription device labeling regulation, which the Eleventh Circuit relied on as the sole basis for affirming preemption of plaintiffs' claims. U.S. Br. 27-28; see Pet. App. 32a-33a. The Solicitor General simply has not asked the right question, and there is no reason for the Court to accept his analysis.

C. Plaintiffs' Failure-to-Warn Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Because common law claims establish state "requirements" potentially subject to preemption, and "any" applicable FDCA requirement can have preemptive effect, all that is left for plaintiffs to argue is that their tort claims would not impose requirements "different from, or in addition to," the applicable FDCA "requirement[s]" such as the warning requirements

described above.[27] But the failure-to-warn claims *would* impose different and additional requirements.

Plaintiffs' first theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr (as distinguished from her physician). R1-3-2; Cross-Pet. Br. 9.[28] The claims alleging failure to warn Mrs. Lohr are preempted, because *any* state-law requirement to warn lay users is "different from, or in addition to," the prescription device labeling regulation. The FDA's regulation defines the Model 4011 as a prescription device—whose distribution is prohibited without a prescription—precisely because adequate directions for lay use are *not possible to prepare* and laypersons cannot adequately understand the risks of its use, regardless of the warnings issued. See 21 C.F.R. 801.109. Yet plaintiffs' claim is that Medtronic should have provided additional warnings directly to Mrs. Lohr. The claim is preempted because it would establish a state requirement "different from, or in addition to," the FDA's regulation, which "exempt[s] [prescription] devices from the requirement that there be directions to a layperson on how to use the product safely." *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994).[29]

---

[27] Plaintiffs erroneously assert that the state requirements must *conflict* with federal requirements to be preempted. See Cross-Pet. Br. 13.

[28] Although plaintiffs assert a claim for failure to warn Mrs. Lohr, no such claim even exists under Florida law. Florida has adopted the "learned intermediary" doctrine, which holds that any duty to warn about a medical device flows to the doctor and not to the patient. See, e.g., *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990).

[29] Plaintiffs' claims for failure to warn Mrs. Lohr are preempted for the additional reason that the FDA has the exclusive authority to require notification to patients that they are using a device that puts them at risk. The FDCA accords the FDA discretion, based on its scientific expertise, to determine whether patients should be notified, or whether "notice to such individuals would present a greater danger to the health of such individuals than no such notification." 21 U.S.C. 360h(a). The statute grants the agency this authority, because in a variety of contexts, warning of device risks

(Footnote continued on next page)

Plaintiffs' second theory of liability is that Medtronic gave inadequate warnings to Mrs. Lohr's physician. The claims asserting this theory also are preempted. First, Florida common law duties to warn the physician are "different from, or in addition to," the requirements of the prescription device labeling regulation. The regulation requires warnings of all "relevant" hazards but also allows omission of warnings if these risks are "commonly known to practitioners licensed by law to use the device." 21 C.F.R. 801.109(c). In contrast, the Florida duty is to provide "fair and adequate" warnings of the device's "inherent * * * dangerous propensities." See, e.g., *Stanley Indus., Inc.* v. *W.M. Barr & Co.*, 784 F. Supp. 1570, 1574 (S.D. Fla. 1992).[30] This duty (premised on the "inherent dangers" of a device) imposes a different standard than federal law, which requires "any relevant" warnings. Furthermore, the Florida duty could *require* warnings that the federal requirement *omits* because practitioners are commonly aware of the risks the warnings describe. 21 C.F.R. 801.109. As a result, the Florida duty is "different from, or in addition to," federal requirements.[31]

(Footnote continued from previous page)
threatens the health of patients, who may be frightened into abandoning use of a life-sustaining device or suffer psychological trauma from a notification.

[30] Plaintiffs assert failure-to-warn theories under both their negligence and strict liability causes of action. Although Florida law recognizes claims for failure to warn under both negligence and strict liability doctrines, the Florida courts have not drawn clear distinctions between the substantive duties imposed by the two types of claims. See, e.g., *Prather* v. *Upjohn Co.*, 797 F.2d 923, 926 (11th Cir. 1986); *Baione* v. *Owens-Illinois, Inc.*, 599 So. 2d 1377, 1378-79 (Fla. Dist. Ct. App. 1992). For purposes of preemption analysis, therefore, plaintiffs' negligence and strict liability failure-to-warn claims should be treated as one.

[31] Three courts of appeals in addition to the court below have cited the prescription device labeling regulation as a basis for FDCA preemption of state common law claims alleging failure to warn. See Pet. App. 33a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 18; *Duvall* v. *Bristol-Myers-Squibb Co.*, 65

(Footnote continued on next page)

Second, the failure-to-warn claims are preempted by the general misbranding requirements of the FDCA barring inadequate warnings. The Solicitor General argues that the generality of the misbranding provisions makes it very difficult to determine whether they impose standards different from plaintiffs' claims. See U.S. Br. 28.[32] That argument is illogical. Plaintiffs' complaint does not assert that Medtronic has violated the federal misbranding provisions, yet it does claim that the common law duty to warn has been breached. R1-3. Plaintiffs' claims therefore rest on the premise that compliance with the federal standard is insufficient, and that Florida tort law required additional and different warnings. By challenging the sufficiency of the federal standard, the state tort duty is *by definition* different, and the claims are preempted. Cf. *McDermott* v. *Wisconsin*, 228 U.S. 115, 132 (1913) (general misbranding provision in FDCA predecessor statute impliedly preempted state food labeling requirement).

Finally, plaintiffs' claims are preempted by the 510(k) requirements. By reviewing labeling submitted in the 510(k) application and clearing the device for marketing, the FDA made the decision that the Model 4011 can be marketed with the labeling submitted, and that Medtronic cannot change the labeling in a manner that could significantly affect safety or effectiveness without further FDA review and clearance. See, e.g., *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399-400 ("[F]or all intents and purposes, [manufacturer] is required to continue to * * * label the device as proposed in its original 510(k) Notification."). Furthermore, the FDA has not exercised its

---

(Footnote continued from previous page)
F.3d 392, 399 (4th Cir. 1995), petition for cert. pending, No. 95-1010; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

[32] One of the misbranding requirements the Solicitor General cites (relating to adequate directions for use) does not apply to the Model 4011 because it is a prescription device. See U.S. Br. 27; 21 C.F.R. 801.109 (exempting prescription devices from requirement to provide adequate directions for use).

authority to require additional warnings after it cleared the Model 4011 for marketing. See 21 U.S.C. 360h(a), (e); 21 C.F.R. 895.25. In contrast, plaintiffs claim that the labeling cleared by the FDA is inadequate, and that Florida common law required Medtronic to give different, and additional, warnings. Section 360k(a) preempts such claims.[33]

III. THE FDCA PREEMPTS PLAINTIFFS' DEFECTIVE MANUFACTURING CLAIMS

In discussing the defective manufacturing claims—as in discussing the labeling claims—plaintiffs, their amici, and the Solicitor General ask the wrong question and, predictably, get the wrong answer. *Numerous* federal requirements govern manufacturing, and plaintiffs' claims would impose different and additional requirements under state law. They are therefore preempted.

---

[33] Because the state duty would require Medtronic to change its warnings and the federal requirements bar such changes without FDA clearance, the failure-to-warn claims would establish requirements in direct conflict with federal law. Like the design claims discussed in Medtronic's opening brief, see Pet. Br. 46 n.24, the failure-to-warn claims would be impliedly preempted even if this Court were to conclude that they are not expressly preempted. See, e.g., *English* v. *General Elec. Co.*, 496 U.S. 72, 79 (1990) (state law is impliedly preempted if "it is impossible for a private party to comply with both state and federal requirements"); *Freightliner Corp.* v. *Myrick*, 115 S. Ct. 1483, 1488 (1995) (existence of an express preemption provision does not foreclose implied preemption arising from actual conflict between federal and state law). Plaintiffs concede that implied preemption doctrine could invalidate their claims under some circumstances. Cross-Pet. Br. 23 n.6. And this Court recently has clarified that implied preemption doctrine applies in significantly broader circumstances than plaintiffs acknowledge. There is implied preemption not only when a federal statute *commands* actions that a state forbids, but also when "the Federal Statute authorizes * * * activities that the State * * * forbids." *Barnett Bank* v. *Nelson*, No. 94-1837 (Mar. 26, 1996), slip op. 5.

A. The FDCA Establishes Substantial Manufacturing Requirements for the Model 4011

1. The GMP Regulations Impose Significant Manufacturing Requirements

The GMP regulations impose significant controls on device manufacture, contrary to plaintiffs' suggestion that they are trivial requirements, "little more than common-sense standards for the production of any product." Cross-Pet. Br. 44.

The FDCA authorizes the FDA to prescribe regulations "requiring that the methods used in, and the facilities and controls used for," the manufacture of a device "conform to current good manufacturing practice * * * to assure that the device will be safe and effective and otherwise in compliance with [the Act]." 21 U.S.C. 360j(f)(1)(A). Although the FDA is ultimately responsible for promulgating these GMP regulations, the statute establishes an expert advisory committee to formulate them. *Id.* § 360j(f)(1)(B). The statute requires that the advisory committee be composed of nine members chosen from local, state, or federal government, the device industry, the health professions, and the general public. *Id.* § 360j(f)(3).[34] These varying interests effectuate the congressional intent by formulating requirements strict enough to ensure safety and effectiveness, but not so strict that they would be "likely to retard innovation, reduce efficiency, and hinder cost control." Device Good Manufacturing Practices Manual, HHS Pub. No. FDA 87-4179 (Nov. 1987) at iv.

The GMP requirements that emerge from this regulatory structure establish critical quality assurance standards for the

---

[34] The statute also ensures broad public participation in the formulation of manufacturing requirements by mandating that the FDA must afford an opportunity for an oral hearing before the agency may promulgate proposed GMP regulations. *Id.* § 360j(f)(1)(B)(ii); 21 C.F.R. 15.1(b). After the regulations are proposed, the public has additional opportunities to participate through notice and comment rulemaking procedures.

medical device industry. These regulations require implementation of a quality assurance program covering all aspects of product manufacture. 21 C.F.R. 820.5. The GMP regulations establish requirements governing training, environmental control, and sanitation (*id.* §§ 820.25, .46, .56); equipment (*id.* §§ 820.60, .61); control of components (*id.* §§ 820.80, .81); production and process controls (*id.* §§ 820.100, .101, .115, .116); packaging and labeling controls (*id.* §§ 820.120, .121, .130); and inspection of finished devices (*id.* §§ 820.160, .161). Documented investigations of device failures also are required under the GMP regulations. *Id.* § 820.162. In addition, record-keeping requirements established in the GMP regulations apply to manufacture of devices. *Id.* §§ 820.180, .181, .182, .184, .185, .195, .198.

There certainly would be no need for the elaborate advisory committee structure described above if the plaintiffs' minimalization of the GMP regulations (Cross-Pet. Br. 44) were correct. In fact, the complexities of the GMP regulations have required the agency to issue hundreds of pages of guidance documents to aid its own investigators and industry in applying the quality assurance standards involved. See, e.g., Device Good Manufacturing Practices Manual, *supra*; FDA Compliance Program Guidance Manual, Transmittal No. 95-30 (Mar. 4, 1995). Furthermore, policing the GMP regulations has become a major thrust of the FDA's compliance program. Frequently, the majority of agency "warning letters" threatening enforcement actions derive from GMP issues, see, e.g., FDA Enforcement Manual Monthly Bulletin at 6 (Nov. 1994), and the FDA often initiates litigation to enforce the regulations, see, e.g., *United States* v. *Undetermined Quantities of Various Articles*, 800 F. Supp. 499 (S.D. Tex. 1992). As the court below properly explained, the agency's enforcement activity "foreclose[s] any suggestion that the GMP regulations are hortatory and without substantive effect." Pet. App. 31a.

2. The 510(k) Process Imposes Significant Manufacturing Requirements

Although the FDA's regulations do not explicitly require submission of manufacturing information in an original 510(k) application, the manufacturing process for a marketed device may not be changed in a manner that could significantly affect safety or effectiveness without 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i).

The FDA has recognized that the 510(k) substantial equivalence requirements are inextricably linked to the GMP requirements in assuring reasonable safety and effectiveness of devices such as the Model 4011. Because the processes under which a device is manufactured fundamentally affect its safety and effectiveness, "both a change in manufacturing processes and a violation of [the GMP regulations] may have a significant impact on the question of substantial equivalence." 58 Fed. Reg. 57,614 (Oct. 26, 1993). As a result, the agency has concluded that a device that is manufactured under processes that constitute significant GMP violations "does not satisfy the criteria for a finding of substantial equivalence" under the FDCA. *Ibid.* The agency therefore enforces both 510(k) and GMP requirements to control device manufacturing.

B. The Federal Manufacturing Requirements Have Preemptive Effect Because They are "Applicable to the Device"

As the discussion at pages 25-27 *supra* explains, any FDCA requirement is preemptive as long as it is "applicable to the device." The 510(k) and GMP requirements described above easily fit within this phrase. In addition, Medtronic's opening brief and the discussion at page 25 *supra* also explain that two other sections of the FDCA refer to the 510(k) requirements as applicable to the device. See Pet. Br. 31-32. One of the same two sections also refers to the GMP requirements established under FDCA § 520(f) (21 U.S.C. 360j(f)) as "appl[icable] to the device," confirming their status as preemptive requirements. See

id. § 360c(d)(2)(A). See also U.S. Br. 24 n.19 (GMP regulations are "requirements" within the meaning of the FDCA preemption provision).

C. Plaintiffs' Defective Manufacturing Claims Are Preempted Because They Would Establish State Requirements "Different From, or in Addition to," Federal Requirements Applicable to the Model 4011

Like the failure-to-warn claims discussed above, plaintiffs' defective manufacturing claims would establish state requirements "different from, or in addition to," applicable federal manufacturing requirements and meet all other criteria mandating preemption under the FDCA.

1. The GMP Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' defective manufacturing claims are preempted, because they would establish requirements "different from, or in addition to," the GMP regulations. Plaintiffs' complaint does not assert that Medtronic has violated the GMP regulations, but it does allege that the company violated the Florida negligence and strict liability standards. R1-3. The premise of plaintiffs' claims therefore is that a device manufactured in accordance with the GMP regulations is not sufficiently safe, and that Medtronic should have used a different manufacturing process. By asserting that Medtronic is exposed to state liability despite its compliance with the GMP regulations, plaintiffs' manufacturing claims necessarily would establish state requirements different from, and in addition to, those federal requirements.[35]

---

[35] The court below and four other courts of appeals have held that the GMP regulations preempt defective manufacturing claims. See Pet. App. 31a; *Mendes* v. *Medtronic, Inc.*, 18 F.3d at 19; *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), cert. denied, 116 S. Ct. 67 (1995); *Duvall* v. *Bristol-Myers-Squibb Co.*, 65 F.3d at 399; *Feldt* v. *Mentor Corp.*, 61 F.3d at 436.

Nonetheless, the Solicitor General argues that there is no way to know whether plaintiffs' manufacturing claims would establish state requirements different from, or in addition to, the GMP requirements, because the federal requirements are phrased in general language that may *overlap* with state tort duties. U.S. Br. 22-25. Although the state and federal requirements may overlap to some extent, there also are areas in which they diverge, such as in the present case, in which plaintiffs allege that Medtronic should pay common law damages despite its compliance with the GMP regulations. As long as the state and federal requirements contain *some* differences, they are "different from" each other, even if they contain some similarities as well. See also Point IV, *infra*.

Furthermore, a comparison of the state and federal requirements at issue confirms their differences. First, plaintiffs' strict liability manufacturing claim would establish a state-law requirement different from the GMP requirements. Under Florida law, a manufacturer is subject to strict liability for distributing a product in a defective condition unreasonably dangerous to foreseeable users and bystanders. *Witt* v. *Norfe, Inc.*, 725 F.2d 1277, 1278 (11th Cir. 1984). In contrast, a manufacturer is liable for producing devices in violation of the GMP regulations even if those devices have no defects and are not at all dangerous to the user. See, e.g., *United States* v. *789 Cases*, 799 F. Supp. 1275, 1286 (D.P.R. 1992) (the FDA need not prove that the devices have defects or cause harm to prove GMP violations). The reason defects and dangers need not be shown is that the GMP regulations have a preventive purpose and are intended to "build in" quality prospectively to minimize the possibility of a defective device. Cf. 43 Fed. Reg. at 31,509 (July 21, 1978) (preamble to GMP regulations).

Second, plaintiffs' negligent manufacturing claim would establish state-law requirements different from the GMP requirements. The state-law duty underlying plaintiffs' negligence claim is a standard of reasonable care in product manufacture, imposed so that products will be reasonably safe for use in a

foreseeable manner. See, e.g., *Witt* v. *Norfe, Inc.*, 725 F.2d at 1278. In contrast, the GMP requirements derive not from what is "reasonable" but instead from "basic principles of quality assurance" that "have as their goal the production of articles that are fit for their intended uses." 43 Fed. Reg. at 31,509. The FDA explains those principles as follows (*ibid.*):

> (1) Quality, safety, and effectiveness must be designed and built into the product; (2) quality cannot be inspected or tested into the finished product; (3) each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications.

At the time the agency first promulgated the GMP regulations, device manufacturers had not yet adopted adequate quality assurance programs. Some firms had no programs at all, and the FDA estimated that the firms that did have programs were complying only with about half of the quality assurance requirements established through the GMP regulations. *Ibid.* As a result, the GMP regulations imposed new and different requirements on manufacturers that had been governed by common law duties before enactment of the MDA. There is no basis whatsoever for suggesting that the GMPs and the common law (which governed device manufacturers before 1976) are identical.

Finally, preemption of plaintiffs' manufacturing claims under the GMP requirements is consistent with the federal statutory structure. The FDCA assigns an expert advisory committee the responsibility for formulating manufacturing requirements. See pp. 32-33, *supra*. In contrast, plaintiffs' common law claims would allow a state judge and jury to determine the methods by which the Model 4011 lead should be manufactured. Preemption of those claims reserves implementation of manufacturing requirements to the federal government in accordance with the statutory procedures, as Congress intended.

2. The 510(k) Requirements Preempt Plaintiffs' Defective Manufacturing Claims

Plaintiffs' claims based on alleged manufacturing defects also are preempted because of the 510(k) requirements described above. Plaintiffs assert that Medtronic's manufacturing process was inadequate, and that it should have used a different process to produce a safer device. On the other hand, the FDCA prohibits the manufacturer of a device cleared through the 510(k) process from changing its manufacturing process in a way that could affect safety or effectiveness significantly without obtaining additional 510(k) clearance. 21 C.F.R. 807.81(a)(3)(i). State requirements that would be imposed through plaintiffs' manufacturing claims therefore are preempted under section 360k(a), because they are different from, or in addition to, the federal regulation requiring FDA clearance for manufacturing changes.[36]

IV. EVEN IF BASED ON FEDERAL STANDARDS, PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THEY WOULD IMPOSE REQUIREMENTS THAT ARE "DIFFERENT FROM, OR IN ADDITION TO," APPLICABLE FEDERAL REQUIREMENTS

In holding that plaintiffs' failure-to-warn and defective manufacturing claims are preempted, the court of appeals stated that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the [federal] statutory standards." Pet. App. 13a-14a. A contrary result would permit lay juries, rather than the expert federal agency, to determine such complex issues as whether a medical device's "labelling and packaging information is incomplete or inaccurate, and if so what label changes, if any, should be made." Pet. App. 13a

---

[36] This conflict between state and federal law also invalidates plaintiffs' defective manufacturing claims under the implied preemption doctrine. See p. 31 n. 33 *supra*.

(quoting *Papas* v. *Upjohn Co.*, 985 F.2d 516, 519 (11th Cir.), cert. denied, 114 S. Ct. 300 (1993)). The Eleventh Circuit's conclusion followed "[e]very circuit court decision addressing this issue under the MDA." Pet. App. 14a.

Plaintiffs' complaint does not assert a claim for violation of federal requirements R 1-3.[37] Nonetheless, plaintiffs contend that their tort claims would be preserved if they were recast as claims that "seek only to enforce federal standards" (Cross-Pet. Br. 45-46), because they would not then impose any requirements that are "different from, or in addition to," the federal requirements applicable to the Model 4011. The United States agrees that identical state requirements are not "different from, or in addition to," the federal requirements, and further maintains that damages remedies based on such identical standards are not "requirements" at all. U.S. Br. 11-15, 22-28.[38]

---

[37] Florida law may not even recognize such a claim. For example, under Florida law, it may well be inappropriate to instruct the jury that the doctrine of negligence per se applies, even if an alleged statutory violation typically constitutes negligence. *Underwriters at LaConcorde* v. *Airtech Servs., Inc.*, 493 So. 2d 428, 431 (Fla. 1986) (Boyd, J., concurring in part and dissenting in part). Furthermore, the Florida courts have not resolved definitively whether negligence per se even applies to violations of administrative regulations as well as to violations of statutes. *Id.* at 430. It is even less clear whether negligence per se applies to violations of federal regulations. See, e.g., *Murray* v. *Briggs*, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990) ("[A]lthough several courts seem comfortable with the concept, we are not satisfied that a federal regulation should necessarily control state-law questions of negligence by enlarging common law duties or creating new duties.") (footnote omitted), review denied, 581 So. 2d 165 (Fla. 1991); see also *Cadillac Fairview of Fla., Inc.* v. *Cespedes*, 468 So. 2d 417, 421 (Fla. Dist. Ct. App.) (OSHA violation not dispositive on state-law questions of negligence or products liability), review denied, 479 So. 2d 117 (Fla. 1985).

[38] As the United States notes, an FDA regulation has interpreted the statutory phrase "different from, or in addition to," as excluding state requirements that are "equal to" or "substantially identical" to the applicable federal requirements. U.S. Br. 12-13 (quoting 42 Fed. Reg. at 30,384); accord 21 C.F.R. 808.1(d)(2). The government, however, notably refrains from asking this Court to defer to that agency pronouncement. A state requirement

(Footnote continued on next page)

In pressing the latter argument, the government purports to rely on the FDA's "consistent[], and reasonabl[e], construction of the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10.

The Court should reject all of these arguments. Plaintiffs' interpretation is contrary to the language and structure of the preemption clause. Their interpretation also is wrong, because it would undermine the congressional intent to establish uniform device requirements. In addition, the government is mistaken in arguing that tort-law damages remedies do not qualify as "requirements." In fact, the FDA on several occasions has indicated that state enforcement provisions and remedies *are* "requirements." Accordingly, plaintiffs' damages claims are preempted even if they were recast as based on federal standards.

A. State Requirements Are "In Addition To" Federal Requirements Even When They Embody Identical Standards

Plaintiffs and the government do not make *any* effort to explain how the phrase "different from, or in addition to," can be read to exclude state requirements that are identical to federal requirements. This is not surprising, because the statutory language is not susceptible to the interpretation they advocate—for at least four reasons.

1. Plaintiffs' interpretation treats the statute as if it refers only to state requirements that are "different" and thus fails to give *any* independent meaning to the phrase "in addition to." But Congress did not limit preemption to state requirements that are "different from" federal requirements; it said that requirements that are either "different from, *or in addition to*," federal requirements are preempted. Each word of a statute must

---

(Footnote continued from previous page)
that is only "substantially identical" to a federal requirement would be—almost by definition—"different from" the federal requirement and therefore plainly preempted.

be afforded some meaning. See, e.g., *United States Department of Treasury* v. *Fabe*, 113 S. Ct. 2202, 2210 n.6 (1993). That basic tenet of statutory construction alone defeats plaintiffs' argument.

As a matter of ordinary usage, a state requirement that is identical in content to a federal requirement could fairly be described as an "addition[al]" requirement (just as a second coat of paint of the same color "adds to" or is "in addition to" the first coat). Indeed, this is the *most natural* reading of the phrase "in addition to." State requirements "add to" federal requirements by imposing another set of substantive rules, even if the content of both sets of rules is the same. The manufacturer's obligation to comply with an identical state requirement is completely independent of any federal-law compliance requirement. And again, the phrase "in addition to" must include *some* requirements that are identical, because that is all that remains after "different" state requirements are preempted. Thus, the language of Section 360k(a) does not preserve state requirements that are identical to federal requirements.

Furthermore, plaintiffs allege that Florida law imposes on Medtronic the *requirement* to pay compensatory damages for a violation of standards identical to the federal standards—a requirement that federal law does not impose.[39] Thus, the phrase "in addition to" encompasses that requirement as well as any state requirement that is identical to the federal requirements.

2. Congress knows how to write a preemption provision preserving identical state requirements, as it did in two other sections of the FDCA. See 21 U.S.C. 343-1(a) (preempting state

---

[39] Under the FDCA, the federal government's potential remedies include seizures, injunctions, civil penalties, criminal penalties, cease and desist orders, and orders requiring recalls, notification of hazards and device repairs, replacements, or refunds. 21 U.S.C. 331-334, 360h. Plaintiffs' demand for payment of damages under state law is a substantial additional requirement different from, and in addition to, these FDCA remedies.

food requirements "not identical to" federal requirements); *id.* § 360ss (preempting state radiation standards "not identical to" federal standards). Similarly, Congress has stated explicitly in other statutes' preemption provisions that identical state requirements are not preempted. See, e.g., 15 U.S.C. 1476(a), 2075(a), 2617(a)(2)(B); 49 U.S.C. 30103(b); 46 U.S.C. 4306. See generally MDMA Br. 19 n.25 (quoting similar statutes). Yet Congress obviously did not use such language in drafting the broader preemption provision of the MDA.

In fact, during its consideration of the MDA, Congress *rejected* two versions of the preemption provision that would have exempted identical state requirements. Both an early House bill and the Senate bill that was sent to conference (where its version of the preemption provision was rejected) provided that state requirements were preempted unless they were "identical to" certain federal requirements. H.R. 9984, 93d Cong., 1st Sess. (1973); 121 Cong. Rec. S 6161 (daily ed. Apr. 17, 1975). Congress, however, significantly broadened this language in the final bill to encompass state requirements that are "different from, or in addition to," federal requirements. If Congress had meant to say that it preserved state law "identical to" federal law, it easily could have—and would have—done so.

3. Other preemption provisions in the U.S. Code confirm that, when Congress directs the preemption of state requirements that are "in addition to" or "different from" federal requirements, it does not intend to spare "identical" state requirements. Indeed, the phrase sweeps so broadly that is has been used to mandate preemption of an entire field of state regulation. See 7 U.S.C. 4817 (in statute "intended to occupy the field of—(1) promotion and consumer education involving pork and pork products; and (2) obtaining funds therefor from pork producers," stating that, during certain periods and with certain exceptions, "[t]he regulation of such activity * * * that is *in addition to or different from* this chapter may not be imposed by a State") (emphasis added); see also *Lynbrook Farms* v. *Smithkline Beecham Corp.*, No. 95-2051, slip op. 2, 6-7, 17 (7th

Cir. Mar. 21, 1996) (affirming field preemption under agency regulation prohibiting state "requirements . . . different from, or in addition to, those imposed by USDA" even though "the conclusion we reach today leaves Lynbrook and similar plaintiffs no remedy for the injuries and losses they have suffered"). In addition, other statutes preempt "additional" or "different" state requirements but provide an explicit *exception* preserving state requirements that are consistent with federal law. See, e.g., 21 U.S.C. 678; *id.* § 1052(a), (b). Congress, of course, made no such exception in the FDCA preemption provision.

4. As plaintiffs acknowledge, there is no express or implied private right of action for violation of the FDCA or related regulations. Cross-Pet. Br. 30-31 (citing *Bailey* v. *Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995)); see also 21 U.S.C. 337 ("[P]roceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."). Congress's omission of a private right of action reflects an intent to reserve enforcement of federal requirements exclusively to the federal government. It is most unlikely that Congress intended to foreclose private enforcement of federal norms but to allow states to permit such private enforcement of identical norms under state law. See MDMA Br. 23-26. For that reason as well, the Court should reject plaintiffs' interpretation.[40]

---

[40] Cf. *Merrell Dow Pharmaceuticals Inc.* v. *Thompson*, 478 U.S. 804, 812 n.10 (1986) ("When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.' "); *Gile* v. *Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.) (claim for FDCA violation barred because no private right of action exists), cert. denied, 115 S. Ct. 429 (1994).

B. Plaintiffs' Construction of the Statute is Inconsistent With the Congressional Intent to Establish Uniform Requirements

Although plaintiffs theorize that it would be possible to cast common law claims so that they necessarily would establish requirements identical to federal standards, their theory departs from reality. The inability of courts to ensure consistency in practice would create an irregular pattern of liability exposure for device manufacturers, undermining the congressional intent to impose uniform requirements. The danger that such a regime would frustrate the fundamental objective of the preemption provision reinforces the conclusion that, if Congress had intended to preserve "identical" state requirements from preemption, it would have said so in the text of the statute.

If the FDCA preserved claims for violation of state standards that are identical to federal requirements, differing *interpretations* of federal requirements inevitably would arise as these claims were adjudicated. There is no reason to expect that a lay jury or state judge interpreting a federal requirement necessarily would reach the same construction as the FDA, particularly in cases such as this one, in which there has been no suggestion that the agency believes its requirements have been violated. The risk that state juries and judges would interpret identical requirements inconsistently or "different[ly]" from the FDA is greatly heightened, moreover, because many federal requirements are cast in relatively broad terms.[41]

---

[41] As administered by the FDA, the federal enforcement scheme established by the statute substantially ensures that the federal government will take uniform positions in litigation involving interpretations of the FDCA and related regulations. The FDA General Counsel's Office must approve all enforcement actions for legal sufficiency (Arthur N. Levine, FDA Enforcement Manual at 71 (Apr. 1994)), and those actions filed in federal court also are coordinated through the Civil Division of the Department of

(Footnote continued on next page)

These varying interpretations would render the state requirements "different" from the federal requirements, and therefore preempted. This Court has made clear that preemption depends upon "the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 526 (1977). The FDA also has acknowledged that a state's *application* of a requirement determines whether it is different from, or in addition to, the federal requirement under the FDCA preemption provision. See, e.g., 43 Fed. Reg. 18,661, 18,663 (May 2, 1978); 21 C.F.R. 808.20(c)(1) (requiring submission of judicial and administrative interpretations in petition for exemption from preemption). As a result, claims premised upon these differing interpretations could not survive preemption. Cf. *Merrell Dow*, 478 U.S. at 815 ("[t]o the extent that petitioner is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, petitioner should be arguing * * * that the FDCA pre-empts state-court jurisdiction" over state common law claims for FDCA violations). The irrational pattern of liability exposure that would emerge from varying case-by-case interpretations of the federal requirements is so inconsistent with the expressed congressional desire to promote uniformity that it is reasonable

---

(Footnote continued from previous page)
Justice. See 28 C.F.R. Pt. O, Subpt. Y, App. Sec. 4(c)(9), (10). This coordination helps assure that judicial interpretations of the FDCA and related regulations are uniform. In contrast, permitting private plaintiffs to adopt and assert their own interpretations of the federal requirements in product liability litigation without any nationwide coordination by, or oversight from, the federal experts would inevitably lead to imposition of differing standards. Indeed, as the United States acknowledges, private plaintiffs could assert that a manufacturer has violated FDCA requirements *even if the FDA disagrees*. U.S. Br. 26.

to conclude that if Congress had intended to preserve "identical" state requirements, it would have said so explicitly.[42]

Furthermore, the extraordinary practical difficulties of such a regime confirm that plaintiffs' construction of the statute is wrong. If a state jury determined that a device's labeling was "false and misleading" under the "federal" standard because it omitted some information, a manufacturer would be obliged to change the labeling at least in that state or else risk additional adverse verdicts (possibly even punitive damages awards). But to effectuate such a change the manufacturer would need clearance from the FDA. The FDA, however, might withhold clearance on the ground that the existing labeling is *not* false and misleading, or because the new information would dilute other warnings that the agency deems more important. Worse yet, it is conceivable that *many* states, acting through common law tort actions purportedly applying general federal requirements to specific devices as part of the "identical" law of each state, would impose *irreconcilable* requirements on a manufacturer. And there is no guarantee that the FDA would decide which conflicting interpretation of federal standards is correct. This pattern of conflicting standards would be wholly inconsistent with the congressional intent to promote uniformity.

---

[42] The Solicitor General suggests that state juries could simply be instructed to determine whether a device's labeling is "false and misleading" or bears "adequate directions for use." U.S. Br. 27. Making a virtue of necessity, the Solicitor General points out that he "cannot say" that a jury's determination of such issues "would of necessity rest on any common-law duty of care that is 'different from, or in addition to,' (21 U.S.C. 360k(a)(1)) the Act's labeling provisions." U.S. Br. 28. That is precisely our point. Under the regime advocated by the government, preemption could be determined, if at all, only after the jury's verdict in a post-trial motion—an odd result indeed (as well as a colossal waste of judicial resouces).

C. The Obligation To Pay Damages Is A "Requirement"

Evidently recognizing that plaintiffs' claims, if successful, would require Medtronic to do something "different from, or in addition to," what federal law requires, the Solicitor General contends that an obligation to pay damages rooted in state tort law is not a "requirement" within the meaning of Section 360k(a). He further suggests the FDA has "consistently, and reasonably, construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. Those assertions are wrong.

1. There is no basis *in the text of the statute* for distinguishing between an obligation to conform a medical device's design, labeling, or manufacture to state-law standards and an obligation to pay damages for the violation of such a standard. Both are "requirements." Indeed, two sections of the FDCA refer to 21 U.S.C. 360h—which is entitled "Notification And Other Remedies" and is devoted exclusively to remedies—as prescribing "requirement[s]." 21 U.S.C. 352(t), 331(q)(1). As the Solicitor General elsewhere concedes (U.S. Br. 24 n.19), something that is described as a "requirement" elsewhere in the FDCA should be regarded as a "requirement" for purposes of the preemption provision. It follows that remedies *are* "requirements."

The distinction drawn by the government is particularly untenable in light of the authority of state attorneys general to obtain equitable remedies for violations of common law duties. See, e.g., *Mayor of Georgetown* v. *Alexandria Canal Co.*, 37 U.S. (12 Pet.) 91, 98 (1838); *State* v. *First Nat'l Bank*, 600 P.2d 406, 421 (Alaska 1982). Under the government's reading, a state could enjoin distribution of a device under its common law for violating a federal requirement, even though the FDA had decided both that the same violation is trivial *and* that continued distribution of the device is in the public interest. See 21 U.S.C. 336 ("Nothing in [the FDCA] shall be construed as requiring the

Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of [the FDCA] whenever he believes that the public interest will be adequately served by a suitable written notice or warning."). There is no reason to attribute to Congress a design that would produce such an absurd result.

2. The United States can draw no support from previous statements of the FDA relating to Section 360k(a). Contrary to the Solicitor General's submission, the FDA has *not* previously "construed the term 'requirement' to refer to substantive, but not remedial, provisions." U.S. Br. 9-10. That novel interpretation is nothing more than an invention of the government's litigators in this case. Indeed, several of the agency pronouncements cited by the government conclusively establish that the agency has recognized that state "remedies" *are* a kind of "requirement" within the meaning of Section 360k(a).

The Solicitor General points to three FDA statements. U.S. Br. 12-13. First, he notes that the FDA has interpreted Section 360k(a) not to preempt *identical* or *substantially identical* state requirements. U.S. Br. 12. That is true but irrelevant, because this interpretation rests not on the word "requirement" but rather on the phrase "different from, or in addition to." 43 Fed. Reg. at 18,663; 42 Fed. Reg. 30,383, 303,84 (June 14, 1977).

Second, the Solicitor General notes that the FDA has said that Section 360k(a)

> does not preempt those State or local *requirements respecting general enforcement*, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments.

21 C.F.R. 808.1(d)(6)(i) (emphasis added), cited in U.S. Br. 13. According to the Solicitor General, this passage demonstrates that the FDA has long recognized the distinction between remedies and substantive requirements. That is doubly incorrect.

The quoted passage, by referring to state enforcement provisions as "requirements," flatly *refutes* the government's assertion (and shows that the FDA *does* regard enforcement provisions as "requirements"). In addition, the FDA's *reason* for concluding that state enforcement provisions are preserved was its former view—which rested on language in the preemption clause *other than* the word "requirement"—that state requirements of "general applicability" are not preempted (a view that the United States elsewhere rejects in its brief). See 42 Fed. Reg. at 30,384; 43 Fed. Reg. at 18,663.

For exactly the same reasons, the 1984 FDA advisory opinion cited by the government (U.S. Br. 13; see Cross-Pet. Br. 12a-13a) actually refutes the agency interpretation claimed in the government's brief. According to the Solicitor General, that FDA letter "made clear that the state 'enforcement provisions' that [the FDA] considers not to constitute 'requirement[s]' include *judicial* remedies sought by private parties to enforce state substantive requirements." U.S. Br. 13. In fact, the letter asserts that remedies *are* requirements, stating that Congress did not intend preemption of "State or local *requirements* respecting general enforcement, *including available legal remedies*, or State or local statutes that only incidentally apply to devices." Cross-Pet. Br. 13a (emphasis added). The agency's reason for reaching this conclusion was its former (and now repudiated) view that requirements of general applicability are not preempted. *Ibid.*

In short, far from "consistently, and reasonably, constru[ing] the term 'requirement' to refer to substantive, but not remedial, provisions" (U.S. Br. 9-10), the FDA has on several occasions indicated that "requirements" include state remedies and enforcement provisions. This Court also should conclude that remedies are state requirements subject to FDCA preemption.

CONCLUSION

The Court should affirm in part the judgment of the Eleventh Circuit and hold that the Federal Food, Drug, and Cosmetic Act preempts plaintiffs' negligence and strict liability claims for failure to warn and defective manufacture regarding the Medtronic Model 4011 cardiac pacemaker lead.

Respectfully submitted,

Arthur R. Miller
1545 Massachusetts Ave.
Cambridge, Massachusetts 02138

Dennis P. Waggoner
HILL, WARD &
HENDERSON, P.A.
P.O. Box 2231
Tampa, Florida 33601

Ronald E. Lund
John W. Borg
Sue R. Halverson
MEDTRONIC, INC.
7000 Central Ave., N.E.
Minneapolis, Minnesota 55432

Daniel G. Jarcho
Counsel of Record
Donald R. Stone
McKENNA & CUNEO, L.L.P.
1575 I Street, N.W.
Washington, D.C. 20005
(202) 789-7500

Kenneth S. Geller
Roy T. Englert, Jr.
Alan E. Untereiner
MAYER, BROWN & PLATT
2000 Pennsylvania Ave., N.W.
Washington, D.C. 20006

Counsel for Cross-Respondent

March 29, 1996